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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/683,537	10/09/2003	Todd Allen Berg	293/034 Div2	2610

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EXAMINER	
SNOW, BRUCE EDWARD	
ART UNIT	**PAPER NUMBER**
3738	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/683,537	BERG ET AL.	
	Examiner	Art Unit	
	Bruce E. Snow	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *108-119 and 143-150* is/are pending in the application.

4a) Of the above claim(s) *115-119* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *108-114,143 and 146-150* is/are rejected.

7)☐ Claim(s) *144, 145* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/30/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 10/26/07 have been fully considered. Applicant has amended claim 1 including, *"each set of fingers formed from a unitary structure*" which fails to defined over Sideris; This limitation is interpreted as a product by process limitation. Referring to Sideris, the first and second sets of fingers where formed of wire which was "unitary structure".

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 146 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The unitary structure comprises a flat sheet is not supported by applicant's original disclosure.

Information Disclosure Statement

The information disclosure statement filed 11/30/07 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is

presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

No translation for DE 2822603 or FR 2641692 was found.

Allowable Subject Matter

Claims 144 and 145 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 108-110, 112, 114, 143, 146 are rejected under 35 U.S.C. 102(e) as being anticipated by Sideris (5,433,727).

Referring to figure 3, Sideris teaches:

108. (Currently Amended) A device for use in closing septal defects comprising:

a medial portion (including elements 26) having a longitudinal axis; and

first and second sets of fingers 18, 14, each set of fingers formed from a unitary structure, the first and second set of fingers mounted on the medial portion and capable of extending substantially radially outward from the axis, the first set of fingers unconnected to the second set of fingers at the radially outward ends and the first set of fingers being spaced an axial distance apart from the second set of fingers on the axis, and wherein only one set of fingers 18 is covered by a web of material 16 (see figure 1) between adjacent ones of the fingers.

Regarding claim 114, see figure 3. Claim 114 is interpreted as positively claiming the device for closing septal defects.

Regarding *"each set of fingers formed from a unitary structure"*, this is a product by process limitation which fails to define any specific structure. Regarding at least claim 143 and 146, the fingers are made of wire which could have been formed from melting down the metal of a tube, sheet, anything.

Claims 108-110, 112, 114, 143, 146, are rejected under 35 U.S.C. 102(e) as being anticipated by Lesh et al (6,152,144).

Referring to at least figures 3a and 3b, Lesh et al teaches:

108. (Currently Amended) A device for use in closing septal defects comprising:

a medial portion 28 having a longitudinal axis; and

first and second sets of fingers 11, 29 each set of fingers formed from a unitary structure, the first and second set of fingers mounted on the medial portion and capable of extending substantially radially outward from the axis, the first set of fingers unconnected to the second set of fingers at the radially outward ends and the first set of fingers being spaced an axial distance apart from the second set of fingers on the axis, and wherein only one set of fingers 11 is covered by a web of material between adjacent ones of the fingers.

Regarding claim 114, see figure 9.

Regarding *"each set of fingers formed from a unitary structure"*, this is a product by process limitation which fails to define any specific structure. Regarding at least claim 143 and 146, the fingers are made of wire which could have been formed from melting down the metal of a tube, sheet, anything.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 111, 113, and 147-150 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sideris (5,433,727).

Sideris teaches the device as described above, however, fails to specifically teach nitinol. It would have been obvious to one having ordinary skill in the art have used nitinol for such a material for it's well known characteristics such as biocompatibility. Regarding silicone, Sideris teaches polyurethane; it would have been obvious to one having ordinary skill in the art have used silicone for such a material for it's well known characteristics such as biocompatibility.

Regarding claims 147-150, Sideris teaches an intra-cardiac device made of wire, but fails to teach what material the wire is made of. It would have been obvious to one skilled in the art to have made the wire of Sideris from nickel titanium alloy, stainless steel, thermoplastic, or elastic material for their known use as cardiac device including stents for their known characteristics including biocompatibility.

Claims 111, 113, and 147-150 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lesh et al (6,152,144).

Lesh et al teaches the device as described above, however, fails to specifically teach nitinol. It would have been obvious to one having ordinary skill in the art have used nitinol for such a material for it's well known characteristics such as biocompatibility. Regarding silicone, it would have been obvious to one having ordinary skill in the art have used silicone for such a material for it's well known characteristics such as biocompatibility.

Regarding claims 147-150, it would have been obvious to one skilled in the art to have made the wire of Sideris from nickel titanium alloy, stainless steel, thermoplastic, or elastic material for their known use as cardiac device including stents for their known characteristics including biocompatibility.

Claims 108-114, 143, 146-150 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kazuyuki et al (EP 1013227, applicant cited 11/30/07) in view of Das (5,334,217).

Kazuyuki et al teaches:

108. (Currently Amended) A device for use in closing septal defects comprising:

a medial portion 3 (connecting member) having a longitudinal axis; and

first set of fingers 2 uncovered by a web;

and a closure member 1 having a web and frame 12. However, Kazuyuki et al is silent regarding the closure member being a second set of fingers, but does teach it can have varying shapes; see page 2, lines 10-15.

Das also teaches a septal defect device which has a closure member 22, 32 which can be many of the same shapes taught by Kazuyuki et al, however, further teaching a star shape as shown in figure 5E. It would have been obvious to one having ordinary skill in the art to have made the closure member of Kazuyuki et al in a star shape as taught by Das as an operable substitution. Therefore, the frame of Kazuyuki et al would be formed of straight portions interpreted as arms which are capable of extending substantially radially outward from the axis.

Claim 111, see page 4, line 23 of Kazuyuki et al.

Claim 113, it would have been obvious to one having ordinary skill in the art have used/tried silicone for such a material for it's well known characteristics such as biocompatibility.

Claim 114, see figure 4.

Regarding at least claim 143 and 146, the fingers are made of wire which could have been formed from melting down the metal of a tube, sheet, anything.

Regarding claims 148-149, it would have been obvious to one skilled in the art to have made the implant form stainless steel or thermoplastic for their known use as cardiac device including septal defect devices, stents, etc. for their known characteristics including biocompatibility.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E. Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

bes

BRUCE SNOW
PRIMARY EXAMINER